EXEMPT CHEMICAL MIXTURES—Continued

Manufacturer	Product name [1]	Form	Date
Cerilliant Corporation ...	R,R(-)-Pseudoephedrine 1.0 mg/ml as free base in one of: 1,2-dimethoxyethane, acetonitrile, acetonitrile: water (≥50% acetonitrile), dimethylformamide, ethylene glycol, isopropanol, methanol, methanol/water (50:50), methanol/dimethyl sulfoxide (80:20) methylene chloride, or tetrahydrofuran.	Liquid	8/2/2007
Cerilliant Corporation ...	S,S(+)-Pseudoephedrine 1.0 mg/ml as free base in one of: 1,2-dimethoxyethane, acetonitrile, acetonitrile: water (≥50% acetonitrile), dimethylformamide, ethylene glycol, isopropanol, methanol, methanol/water (50:50), methanol/dimethyl sulfoxide (80:20), methylene chloride, or tetrahydrofuran.	Liquid	8/2/2007
E.I. DuPont deNemours & Co.	RC–5156	Liquid	4/22/2005
E.I. DuPont deNemours & Co.	VH–6037	Liquid	4/22/2005
Hawthorne Products, Inc.	Sole Pack Hoof Dressing	Paste	8/14/2007
Hawthorne Products, Inc.	Sole Pack Hoof Packing	Paste	8/14/2007
Quality Assurance Service Corporation.	10 to 1000 nanograms per milliliter of ephedrine in blood, serum, or urine.	Liquid	9/26/2007
Quality Assurance Service Corporation.	10 to 1000 nanograms per milliliter of pseudoephedrine in blood, serum, or urine.	Liquid	9/26/2007
Quality Assurance Service Corporation.	10 to 1000 nanograms per milliliter of phenylpropanolamine in blood, serum, or urine.	Liquid	9/26/2007
Reichhold, Inc	Beckosol® 12021–00 AA–200, IA–441, P531–T	Liquid	5/05/2005
Reichhold, Inc	Urotuf® L06–30S, F78–50T	Liquid	5/05/2005
Reichhold, Inc	Beckosol AA–220	Liquid	6/14/2005
Waterbury Companies, Inc.	Waterbury 332500	Liquid	4/11/2005
Waterbury Companies, Inc.	Waterbury 332762	Liquid	4/11/2005
Waterbury Companies, Inc.	Waterbury 332400	Liquid	4/11/2005
Waterbury Companies, Inc.	Waterbury 346201	Liquid	4/11/2005

[1] Designate product line if a group.

[68 FR 23204, May 1, 2003, as amended at 75 FR 10681, Mar. 9, 2010; 75 FR 53869, Sept. 2, 2010]

§ 1310.14 Removal of exemption from definition of regulated transaction.

The Administrator finds that the following drugs or groups of drugs are being diverted to obtain a listed chemical for use in the illicit production of a controlled substance and removes the drugs or groups of drugs from exemption under §1300.02(b)(28)(i)(D) of this chapter pursuant to the criteria listed in §1310.10 of this part:

(a) Nonprescription drugs containing ephedrine, its salts, optical isomers, and salts of optical isomers.

(b) Nonprescription drugs containing phenylpropanolamine, its salts, optical isomers, and salts of optical isomers.

(c) Nonprescription drugs containing pseudoephedrine, its salts, optical isomers, and salts of optical isomers.

[75 FR 38922, July 7, 2010]

§ 1310.16 Exemptions for certain scheduled listed chemical products.

(a) Upon the application of a manufacturer of a scheduled listed chemical product, the Administrator may by regulation provide that the product is exempt from part 1314 of this chapter if the Administrator determines that the product cannot be used in the illicit manufacture of a controlled substance.

(b) An application for an exemption under this section must contain all of the following information:

(1) The name and address of the applicant.

(2) The exact trade name of the scheduled listed chemical product for which exemption is sought.

(3) The complete quantitative and qualitative composition of the drug product.

(4) A brief statement of the facts that the applicant believes justify the granting of an exemption under this section.

(5) Certification by the applicant that the product may be lawfully marketed or distributed under the Federal, Food, Drug, and Cosmetic Act.

(6) The identification of any information on the application that is considered by the applicant to be a trade secret or confidential and entitled to protection under U.S. laws restricting the public disclosure of such information by government employees.

(c) The Administrator may require the applicant to submit additional documents or written statements of fact relevant to the application that he deems necessary for determining if the application should be granted.

(d) Within a reasonable period of time after the receipt of a completed application for an exemption under this section, the Administrator shall notify the applicant of acceptance or non-acceptance of the application. If the application is not accepted, an explanation will be provided. The Administrator is not required to accept an application if any of the information required in paragraph (b) of this section or requested under paragraph (c) of this section is lacking or not readily understood. The applicant may, however, amend the application to meet the requirements of paragraphs (b) and (c) of this section.

(e) If the application is accepted for filing, the Administrator shall issue and publish in the FEDERAL REGISTER an order on the application, which shall include a reference to the legal authority under which the order is based. This order shall specify the date on which it shall take effect.

(f) The Administrator shall permit any interested person to file written comments on or objections to the order. If any comments or objections raise significant issues regarding any findings of fact or conclusions of law upon which the order is based, the Administrator shall immediately suspend the effectiveness of the order until he may reconsider the application in light of the comments and objections filed. Thereafter, the Administrator shall reinstate, revoke, or amend the original order as deemed appropriate.

[71 FR 56024, Sept. 26, 2006]

§ 1310.21 Sale by Federal departments or agencies of chemicals which could be used to manufacture controlled substances.

(a) A Federal department or agency may not sell from the stocks of the department or agency any chemical which, as determined by the Administrator of the Drug Enforcement Administration, could be used in the manufacture of a controlled substance, unless the Administrator certifies in writing to the head of the department or agency that there is no reasonable cause to believe that the sale of the specific chemical to a specific person would result in the illegal manufacture of a controlled substance. For purposes of this requirement, reasonable cause to believe means that the Administration has knowledge of facts which would cause a reasonable person to reasonably conclude that a chemical would be diverted to the illegal manufacture of a controlled substance.

(b) A Federal department or agency must request certification by submitting a written request to the Administrator, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address. A request for certification may be transmitted directly to the Office of Diversion Control, Drug Enforcement Administration, through electronic facsimile media. A request for certification must be submitted no later than fifteen calendar days before the proposed sale is to take place. In order to facilitate the sale of chemicals from Federal departments' or agencies' stocks, Federal departments or agencies may wish to submit requests as far in advance of the fifteen calendar days as possible. The written notification of the proposed sale must include:

(1) The name and amount of the chemical to be sold;

(2) The name and address of the prospective bidder;

(3) The name and address of the prospective end-user, in cases where a sale is being brokered;

(4) Point(s) of contact for the prospective bidder and, where appropriate, prospective end-user; and

(5) The end use of the chemical.